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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,376

05/02/2006

Claus Harder

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21324 7590 05/29/2008  
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EXAMINER

GANESAN, SUBA

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

05/29/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com  
akron-docket@hotmail.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,376	<b>Applicant(s)</b> HARDER ET AL.	
	<b>Examiner</b> SUBA GANESAN	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Response to Pre-Appeal Brief Request for Review***

1. Applicant's pre-appeal brief request for review is persuasive. Therefore, the finality of the last action is withdrawn. This action is non-final.

### ***Response to Arguments***

2. Applicant's arguments with respect to claims 1-5 and 9-11 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims **1-4, 9-11** are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (Pub. No.: US 2003/0083646).
2. Sirhan discloses a stent with a coating system (para 18, 20) comprising one or more polymer carriers (para 26, 27) and at least one pharmaceutically active substance (para 17) wherein a concentration of the pharmaceutically active substance varies in the longitudinal direction of the stent (para 34, "areas (e.g., distal and proximal ends of the device) having variable thickness of both the source and the rate-controlling element to allow for slower or faster release," also see para 135). The polymer carrier is

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biodegradable (para 36). The degradation behavior of the carrier serves to differentiate the local elution characteristic (para 40, 45-46, for example). The concentration of the pharmaceutically active substances is greater adjacent the face surfaces than in a middle portion of the stent (para 34).

3. With respect to claims 9-11, Sirhan discloses a stent with a coating system comprising one or more polymer carriers and at least one pharmaceutically active substance, where a material modification (thickness) of the at least one carrier varies in the longitudinal direction (para 34). With respect to claim 11, Sirhan discloses an additive to delay degradation of the polymer carrier (para 40, 41, the polymer carrier is a rate-controlling element, coupled with another layer of rate-controlling element).

4. Claims **1-5**, are rejected under 35 U.S.C. 102(b) as being anticipated by Wang (Pub. No.: US 2002/0055769).

5. Wang discloses a stent with a coating system comprising a polymer carrier and a pharmaceutically active substance, wherein a concentration of the pharmaceutically active substance varies in the longitudinal direction (abstract, fig. 1. and para 44 and 46). The polymer carrier is biodegradable (para 32) and degradation behavior can differentiate the local elution characteristics (para 42). The concentration of the pharmaceutically active substances is greater adjacent the face surface than the middle (para 43). The stent can further comprise a plurality of pharmaceutically active substances wherein a concentration of a first pharmaceutically active substance is greater adjacent the face surfaces than in a middle portion of the stent (see sleeve para 68) and wherein a concentration of a second pharmaceutically active substance is

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greater in a middle portion of the stent (para 44 and fig. 12, noting that with 80% of the stent coated, the concentration would be higher at a portion of the middle of the stent due to the increased density of the stent compared to the “loose” ends).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774